

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ALBANY DIVISION

CITY OF DAWSON, GEORGIA,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY, INC.; TEVA
PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON &
JOHNSON; NORAMCO,
INC.; JANSSEN PHARMACEUTICALS,
INC.; ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC; WATSON
LABORATORIES, INC.; ACTAVIS LLC;
ACTAVIS PHARMA, INC.;
MALLINCKRODT PLC; MALLINCKRODT
LLC; AMERISOURCEBERGEN DRUG
CORPORATION; CARDINAL HEALTH,
INC.; and McKESSON CORPORATION,

Defendants.

CIVIL ACTION FILE
NO. _____

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES

NOW COMES Plaintiff, City of Dawson, a municipal corporation of the State of Georgia (“Plaintiff”), and brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt LLC;

McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively “Defendants”) and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent, or will be spent, because of Defendants’ false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.¹ Such economic damages were foreseeable to Defendants and were sustained because of Defendants’ intentional and/or unlawful actions and omissions.

2. Opioids are a class of drug that bear a high risk of abuse and addiction. In recent years they have been widely diverted and improperly used. The number of Americans addicted to and overdosing on opioids has exploded, reaching the levels of epidemic and creating a public health crisis.

3. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids and turned patients into drug addicts for their own corporate profit. They accomplished this through a multitude of deceptive practices which included aggressive and inaccurate or misleading advertising, promoting false and unsupported conclusions in the scientific community through third-parties,

¹ As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

² Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

concealing the dangers of opioids, and encouraging the over prescription of their products. Such actions were intentional and/or unlawful and had the effect of broadly corrupting the way in which prescription opioids were prescribed throughout the entire country.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

II. THE PARTIES

A. Plaintiff, City of Dawson, Georgia

6. Plaintiff is a municipal corporation organized under the laws of the State of Georgia and is the county seat of Terrell County, Georgia.³ Plaintiff has all the powers of local self-government and home rule and all other powers possible for a city to have under the constitution of the state of Georgia, and the laws of the state of Georgia.

7. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity, and mortality have created a serious public health and safety crisis for the city and the country constituting a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance for the city and the country.

8. The distribution and diversion of opioids into Georgia (“the State”), and into City of Dawson and surrounding areas (collectively, “Plaintiff’s Community”), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

³ See Ga. Const. art. IX, § 2, ¶ 2; O.C.G.A. § 36-30-1, et. seq.

9. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*,: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid crisis; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered, directly by the Plaintiff.

10. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct. Plaintiff is authorized by law to abate any nuisance and prosecute in any court of competent jurisdiction any person who creates, continues, contributes to, or suffers such nuisance to exist and prevent injury and annoyance from such nuisance.

11. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein.

B. Defendants

1. Manufacturer Defendants.

12. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn, or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured

and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

13. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware and can be served at its principal place of business located at One Stamford Forum, Stamford, Connecticut, 06901.

14. PURDUE PHARMA INC. is a New York corporation and can be served at its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut, 06901.

15. THE PURDUE FREDERICK COMPANY is a Delaware corporation and can be served at its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut, 06901.

16. At all relevant times, Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company, Inc. (collectively, “Purdue”) are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

17. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania and can be served by delivering a copy of the Summons and Complaint to its registered agent located at 3411 Silverside Road Tatnall Building STE 104, Wilmington, Delaware, 19810. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as

Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”⁴ Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁵ In 2008, Cephalon, Inc. pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay \$425 million.⁶

18. TEVA PHARMACEUTICAL INDUSTRIES LTD. (“Teva Ltd.”) is an Israeli company with its principal executive offices located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva Ltd. wholly owns Cephalon, Inc. Teva Ltd. may be served at the principal executive office of their American branches and/or subsidiaries located at 1090 Horsham Road, Attention: Deborah Griffin, North Wales, Pennsylvania, 19454.

19. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a wholly-owned subsidiary of Teva Ltd. and is incorporated under the laws of the State of Delaware, with its principal place of business in North Wales, Pennsylvania. Teva USA can be served by delivering

⁴ *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s0301bl.pdf.

⁵ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s0151bl.pdf.

⁶ Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

a copy of the Summons and Complaint to its registered agent for service in Georgia, Corporate Creations Network, Inc. located at 2985 Gordy Parkway, 1st Floor, Marietta, Georgia, 30066.

20. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon, Inc. branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon, Inc. opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.⁷ Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon, Inc. acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora.⁸ Teva Ltd. operates in the United States through its subsidiaries Cephalon, Inc. and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015. Upon information and belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd.,

⁷ E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited May 10, 2018).

⁸ Teva Ltd., Annual Report (Form 20) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively herein as “Cephalon.”

21. JOHNSON & JOHNSON (J&J), is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933. J&J was the corporate parent of Janssen Pharmaceutica Inc. and Ortho-McNeil, Inc., which J&J consolidated into one group that became Ortho-McNeil-Janssen Pharmaceuticals, Inc. Ortho-McNeil-Janssen Pharmaceuticals, Inc. then changed its name to Janssen Pharmaceuticals, Inc. in 2011.

22. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business located in Titusville, New Jersey. Janssen Pharmaceuticals, Inc. is the current corporate identity of the entities previously known as JANSSEN PHARMACEUTICA INC. and ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC. Janssen Pharmaceuticals, Inc. can be served by delivering a copy of the Summons and Complaint to its registered agent for service in Georgia, C T Corporation System located at 289 S. Culver St., Lawrenceville, Georgia, 30046.

23. NORAMCO, INC. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware, with its principal place of business in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco can be served by delivering a copy of the Summons and Complaint to its registered agent for service in Georgia, C T Corporation System located at 289 S. Culver St., Lawrenceville, Georgia, 30046. Noramco is or had been part of J&J’s opium processing by making active pharmaceutical ingredients (“APIs”) for opioid painkillers.

24. J&J, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Noramco (referred to collectively herein as “Janssen”) have, or are, engaged in the manufacturing, promoting, selling, and distributing of drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

25. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business located at 1400 Atwater Drive, Malvern, Pennsylvania, 19355.

26. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation registered to do business in Georgia with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. can be served by delivering a copy of the Summons and Complaint to its registered agent for service in Georgia, C T Corporation System located at 289 S. Culver St., Lawrenceville, Georgia, 30046.

27. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (referred to collectively as “Endo”) develop, market, and sell prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

28. ALLERGAN PLC is a public limited company incorporated in Ireland with its corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland. Allergan PLC may be served at its U.S. administrative headquarters located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. Allergan PLC is the current corporate identity of former entities known as ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., and ACTAVIS, INC. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company retained the name Actavis, Inc., but then changed that name to Actavis PLC in October 2013. Similarly, Actavis PLC acquired Allergan PLC in March 2015, and the combined company adopted the corporate identity of Allergan PLC.

29. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Parsippany, New Jersey and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Watson Laboratories, Inc. may be served by delivering a copy of the Summons and Complaint to its registered agent located at 8275 South Eastern Avenue, #200, Las Vegas, Nevada, 89123.

30. ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation registered to do business in Georgia with its principal place of business located in Parsippany, New Jersey. Actavis Pharma, Inc. can be served by delivering a copy of the Summons and Complaint to its registered agent for service in Georgia, Corporate Creations Network, Inc. located at 2985 Gordy Parkway, 1st Floor, Marietta, Georgia, 30066. Actavis Pharma, Inc. is the current corporate identity of the corporation formerly known as WATSON PHARMA, INC. and is owned by Allergan PLC.

31. ACTAVIS LLC is a Delaware limited liability company which is also owned by Allergan PLC. Actavis LLC may be served by delivering a copy of the Summons and Complaint to its registered agent located at 3411 Silverside Road, Tatnall Building, STE 104, Wilmington, Delaware, 19810.

32. Allergan PLC uses each of these subsidiaries to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are all referred to collectively herein as “Actavis.”

33. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

34. MALLINCKRODT PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and can be served at its U.S. headquarters located at 675 McDonnell Boulevard, Hazelwood, Missouri, 63042.

35. MALLINCKRODT LLC is a Delaware limited liability company licensed to do business in Georgia with its principal place of business located in Hazelwood, Missouri. Mallinckrodt LLC can be served by delivering a copy of the Summons and Complaint to its registered agent for service in Georgia, Corporate Creations Network, Inc. located at 2985 Gordy Parkway, 1st Floor, Marietta, Georgia, 30066. Mallinckrodt LLC is a wholly owned subsidiary

of Mallinckrodt PLC. Mallinckrodt PLC and Mallinckrodt LLC are referred to collectively herein as “Mallinckrodt.”

36. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017 Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

2. Distributor Defendants

37. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Distributors universally failed to comply with federal and/or state law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff’s Community.

38. McKESSON CORPORATION (“McKesson”) at all relevant times, operated as a licensed pharmacy wholesaler in Georgia. McKesson is registered with the Georgia Secretary of State as a Delaware corporation with its principal place of business located in San Francisco, California. McKesson can be served by delivering a copy of the Summons and Complaint to its registered agent for service in Georgia, Corporation Service Company, located at 40 Technology Parkway South, #300, Norcross, Georgia, 30092.

39. CARDINAL HEALTH, INC. (“Cardinal”) at all relevant times, operated as a licensed pharmacy wholesaler in Georgia. Cardinal is registered with the Georgia Secretary of State through various entities including Cardinal Health 100, Inc., Cardinal Health 110, LLC,

and Cardinal Health Pharmacy Services, LLC. Cardinal is an Indiana corporation with its principal place of business located at 7000 Cardinal Place, Dublin, Ohio, 43017. Cardinal may be served in Georgia through C T Corporation System who is the registered agent for all of Cardinal's many subsidiaries registered in Georgia through which Cardinal operates. C T Corporation System is located at 289 S Culver St, Lawrenceville, Georgia, 30046-4805.

40. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") at all relevant times, operated as a licensed pharmacy wholesaler in Georgia. AmerisourceBergen is registered with the Georgia Secretary of State as a Delaware corporation and its principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen can be served by delivering a copy of the Summons and Complaint to its registered agent for service in Georgia, C T Corporation System, located at 289 S Culver St, Lawrenceville, Georgia, 30046-4805.

41. The data which reveals and/or confirms the identity of each wrongful opioid distributor is stored in the DEA's confidential ARCOS database. This data is not available to the public and has only recently become available to litigants on a limited basis through court order.⁹ Neither the DEA¹⁰ nor the wholesale distributors¹¹ will voluntarily disclose the data necessary to

⁹ See *Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

¹⁰ See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

¹¹ See Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

42. Consequently, Plaintiff has named the three (3) wholesale distributors which dominate 85% of the market share for the distribution of prescription opioids: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. The “Big 3” are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs.¹² Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into its community and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiff names each of the “Big 3” herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

III. JURISDICTION & VENUE

43. This court has diversity subject matter jurisdiction over this action under 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, and there exists complete diversity between the parties, *i.e.* no defendant is a citizen of Plaintiff’s home state Georgia.

¹² See *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors).

44. Additionally, 28 U.S.C. § 1331 grants this court federal question subject matter jurisdiction over Plaintiff's "RICO" claims as they arise under the Racketeer Influenced and Corrupt Organizations Act (RICO).¹³ This allows the Court to also exercise supplemental jurisdiction over Plaintiffs' other claims because they form part of the same case or controversy as the federal RICO claims.¹⁴

45. This Court has personal jurisdiction over Defendants because Georgia law grants jurisdiction over nonresidents who transact business within the state, commit a tortious act or omission within the state, or cause a tortious injury that occurs within the state if they derive a substantial source of revenue from goods consumed within the state or engage in persistent conduct within the state.¹⁵ Defendants, by and through their authorized agents, servants and employees, regularly transacted business in Georgia; manufactured, supplied, and distributed opioids in Georgia from which they received substantial revenue; and further, through their acts and omissions, tortiously caused injuries in Georgia by engaging in a persistent course of conduct in Georgia which violated Georgia law. Because Defendants purposefully directed their actions toward Georgia, consented to be sued in Georgia by registering an agent for service of process, and/or consensually submitted to the jurisdiction of Georgia when obtaining a manufacturer or distributor license, they have the requisite minimum contacts with Georgia for this Court to constitutionally assert personal jurisdiction over them.

46. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. 1965(b). The Court may exercise nation-wide jurisdiction over the named Defendants where the

¹³ 18 U.S.C. § 1961, et seq.

¹⁴ 28 U.S.C. § 1367(a).

¹⁵ O.C.G.A. § 9-10-91.

“ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial.¹⁶

47. Venue is proper in the Albany Division of this District under Middle District of Georgia Local Rule 3.4 because Plaintiff resides in Terrell County and the claim arose in and around Terrell County. Venue is further proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District.¹⁷

IV. FACTUAL ALLEGATIONS

A. The Opioid Crisis

48. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.¹⁸ This increase in abuse of prescription drugs and its ensuing social harm has reached crisis levels, leading the Centers for Disease Control and Prevention to declare a “prescription painkiller overdose epidemic” in 2011.¹⁹

¹⁶ See, e.g., *Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher’s Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

¹⁷ 28 U.S.C. §§ 1391(b); § 1965(a).

¹⁸ See Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

¹⁹ Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html

49. This crisis was caused by Defendants' intentional wrongful conduct and/or negligence. Among other things, Defendants orchestrated a systematic campaign of misinformation to obscure the dangers of their opioid products and either intentionally or recklessly ignored blatant signs of illicit opioid orders in direct contravention of both federal and state law. As a result of Defendants actions, opioids were drastically overprescribed – both in good faith by well-meaning physicians who were duped by Defendants' misrepresentations and by unscrupulous “pill mills” taking advantage of the gap in oversight created by Defendants' willful blindness. Innocent sufferers of pain were turned into addicts by following their doctors' orders, and the black market for illicit drugs was flooded with an enormous supply of pharmaceutical narcotics. Defendants' blatant profiteering has created a class of newly-minted drug addicts, many of whom eventually turn to heroin, leaving in their wake broken homes, broken families, and broken lives.

50. Sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014, but there has not been an overall change in the amount of pain Americans report.²⁰ By 2014 the rate of opioid prescribing in America had reached **75.6 prescriptions per 100 persons**, and 1 in 5 Americans had a prescription for opioids.²¹

²⁰ Centers for Disease Control and Prevention, *Prescribing Data*, <https://www.cdc.gov/drugoverdose/data/prescribing.html> (last visited May 9, 2018).

²¹ Centers for Disease Control and Prevention, *Annual Surveillance Report of Drug-Related Risks and Outcomes — United States, 2017*, Published August 31, 2017, Accessed May 9, 2018 from <https://www.cdc.gov/drugoverdose/pdf/pubs/2017cdc-drug-surveillance-report.pdf>

51. From 1999 to 2016 the number of overdose deaths involving prescription opioids in America increased *five times over*, claiming the lives of *over 200,000 individuals* in that time period.²²

52. In addition to this chilling death toll, prescription opioids have led to hospitalizations, the need for higher law enforcement utilization, and the need for drug addiction treatment programs, all of which has imposed great cost upon Plaintiff.

53. Unfortunately, it is too late to reverse this substance abuse catastrophe by merely reigning in opioid prescription. The prescription drug epidemic continues to rage but has also given rise to similarly drastic increases in abuse of heroin (an opioid itself) and illegally manufactured synthetic opioids, resulting in a full-blown *opioid crisis*. This crisis, while sparked by Defendants, is now beyond their control.

54. Throughout the early years of the prescription opioid epidemic, the number of deaths resulting from heroin overdoses held relatively constant but began to slowly rise in 2007.²³ Then in 2010, heroin death rates skyrocketed, increasing fivefold from 2010 to 2016.²⁴ Perhaps even more shocking and disturbing, is the fact that from 2013 to 2016, the number of deaths associated with synthetic opioids has roughly doubled *each year* (literally growing exponentially), causing more deaths than either heroin or semi-synthetic painkillers in 2016.²⁵

²² Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data*, <https://www.cdc.gov/drugoverdose/data/overdose.html> (last visited May 9, 2018).

²³ Office of National Drug Control Policy, *National Drug Control Strategy Data Supplement 2016*, p. 137; Josh Katz, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, N.Y. TIMES, Sept. 2, 2017, <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html>

²⁴ Centers for Disease Control and Prevention, *Heroin Overdose Data*, <https://www.cdc.gov/drugoverdose/data/heroin.html>

²⁵ National Institute on Drug Abuse, *Overdose Death Rates*, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

55. Despite trends of declining use and deaths in every other category of drug, the wild growth in opioid abuse in recent years has driven drug overdoses to overtake automobile accidents as the number one external killer of Americans for the first time since automobiles entered mainstream use.²⁶ In 2016, drugs killed more Americans in a single year than the entire Vietnam War.²⁷

56. The relative timing of these unprecedented surges in opioid-related deaths obviously *suggests* a causal link between Defendants' products and illicit opiates, but there is an abundance of evidence, which when taken together, clearly establishes that causal link.²⁸

57. The National Institute on Drug Abuse identifies misuse and addiction to opioids as a "serious national crisis that affects public health as well as social and economic welfare."²⁹ The economic burden of prescription opioid use alone is \$78.5 *billion* a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.³⁰

58. Georgia, and the City of Dawson in particular, have borne these costs. In 2015, 918 people died from opioid overdoses in the State of Georgia, more than *seven* times the number

²⁶ See Center for Behavioral Health Statistics and Quality, *Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health*, HHS Publication No. SMA 15-4927, NSDUH Series H-50, (2015); Centers for Disease Control and Prevention, *Drug Poisoning Deaths in the United States, 1980–2008*, <https://www.cdc.gov/nchs/data/databriefs/db81.htm>.

²⁷ German Lopez, *In One Year, Drug Overdoses Killed More Americans than the Entire Vietnam War Did*, Vox (Jun 8, 2017), <https://www.vox.com/policy-and-politics/2017/6/6/15743986/opioid-epidemic-overdose-deaths-2016>.

²⁸ George Jay Unick et al., *Intertwined Epidemics: National Demographic Trends in Hospitalizations for Heroin- and Opioid-Related Overdoses, 1993–2009*, PLoS ONE 8(2): e54496. doi:10.1371/journal.pone.0054496 (2013); Wilson M. Compton et al., *Relationship between Nonmedical Prescription-Opioid Use and Heroin Use*, 374 N. Eng. J. Med. 154 (2016).

²⁹ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

³⁰ *Id.*

who died from the same cause in 1999.³¹ Terrell County, in which Dawson is the county seat and in which Dawson makes up nearly half the county's population, has a disproportionately high number of both residents who report abusing painkillers and who report being addicted to drugs.³² This is perhaps unsurprising in light of the fact that, for the last decade, the City of Dawson and Terrell County's western county neighbor has consistently maintained opioid prescription rates exceeding 138 for every 100 residents, and reaching as many as 191 in 2013.³³ Furthermore, the healthcare costs of the opioid crisis have hit Dawson's local government especially hard due to the fact that the percentage of Terrell County residents who are uninsured is twice that of the national percentage.³⁴

59. While the public pays the catastrophic costs of this crisis, the suppliers of opioids reap massive rewards, earning \$8.6 billion in 2016, with profits continuing to rise.³⁵

60. Defendants wrongful and/or illegal actions and omissions are the proximate cause of this opioid crisis, which has wreaked havoc across the country generally, and specifically in Plaintiff's state and community, causing great and costly damages to Plaintiff's community including prescription opioid abuse, addiction, morbidity and mortality.

61. The opioid epidemic in Georgia, and in Plaintiff's Community specifically, remains an immediate hazard to public health and safety.

³¹ <https://oasis.state.ga.us/oasis/webquery/qryDrugOverdose.aspx>

³² The Foundation for AIDS Research, *Georgia Opioid Epidemic*, <http://opioid.amfar.org/GA>.

³³ Centers for Disease Control and Prevention, *U.S. County Prescribing Rates, 2010*, <https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html>.

³⁴ The Foundation for AIDS Research, *Georgia Opioid Epidemic*, <http://opioid.amfar.org/GA>.

³⁵ Esme Deprez and Paul Barrett, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, Bloomberg (Oct. 5, 2017), <https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry>.

62. The opioid epidemic in Plaintiff's Community is a public nuisance and remains unabated.

B. Manufacturing Defendants' Campaign of Misinformation

63. In an effort to increase their profits by maximizing the sale of their prescription opioid products, Manufacturing Defendants have orchestrated a campaign of misinformation about the safety and efficacy of prescription opioids as pain relievers that came to pervade the entire national medical community. This deceptive marketing campaign was carried out not only through the statements directly published by these Defendants, but also through third-parties who gave the false impression of being financially disinterested in opioids, while in fact they were receiving funds from, and working to further the interests of, Manufacturing Defendants.

64. Manufacturing Defendants made direct and indirect misrepresentations to physicians and consumers regarding the safety and efficacy of their opioid products. These misrepresentations comprised and espoused a "core message" developed by Manufacturing Defendants at their corporate headquarters, where they oversaw national development and dissemination of that message through marketing materials, sales representatives, and third-parties.

65. These misrepresentations were so effective that they infected an entire subset of the field of medicine, becoming for a time recognized as authoritative.

66. This manipulation of the medical community's understanding of opioids was not only intentional, it was malicious. Defendants sought to confound rightly cautious perceptions of opioid medications that would have protected the public from this epidemic *for the precise reason that they wanted to prey upon the public for profit.*

67. Manufacturing Defendants' conscious indifference is further evinced by the fact that their marketing targeted vulnerable patient populations like the elderly and veterans despite the fact that both have characteristics that make them more likely to suffer a negative outcome as a result of opioid use.³⁶

68. Manufacturing Defendants also targeted primary care doctors, who have less knowledge of the risks of opioids and less experience treating pain. This indicates that Defendants were aware that their marketing claims would not stand up to scrutiny.

69. Manufacturer Defendants' intentional profiteering at the expense of public health and safety can further be seen in their outright refusal to fulfill their legal obligations to help identify illicit prescribers of their products, presumably because the elimination of sales to those providers would reduce their revenue. For example, Purdue went well beyond the mere passive dereliction of its duty to help discover such prescribers and other diversion enterprises. Purdue did compile a database of doctors suspected of inappropriately prescribing its drugs but **did not report these doctors** to state medical boards or law enforcement authorities (as it was legally obligated to do) *or even cease marketing to them*. Instead, it used that information to argue that generic OxyContin should be banned due to its risk for abuse. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to act – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more

³⁶ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 2, 25 [hereinafter 2016 CDC Guideline], <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.³⁷

70. Not only was it foreseeable that Manufacturer Defendants' conduct would lead to the opioid crisis which that conduct did eventually cause and is now plaguing our nation, but Defendants continued their wrongful actions well after it was evident that they had created an epidemic of drug abuse, addiction, and death.

1. Manufacturing Defendants' Use of Third-Parties

71. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Because of the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

72. Over many years Manufacturer Defendants were able to shift the prevailing opinion of prescription opioids within the medical community through a concerted marketing campaign which employed false and misleading information and tactics. This resulted in drastically higher rates of prescription, which is both the driver and limiter of their products' demand.

³⁷ Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

73. Manufacturer Defendants accomplished this in part through an indirect marketing campaign in which they used two speciously impartial avenues of delivery to advance their dangerously inaccurate message about the safety and efficacy of prescription opioids. The first of these consisted of physicians claiming some degree of expertise in the field of opioids or pain management. Such physicians are known as “key opinion leaders” (KOLs). The second avenue consisted of industry organizations posing as neutral and credible professional societies and patient advocacy groups, but which were in fact funded by and serving the interests of defendants (referred to hereinafter as “Front Groups”).

74. Defendants collectively and individually funded, assisted, and directed these KOLs and front groups. In return, the KOLs and Front Groups promoted Defendants’ interests by promoting a narrative that downplayed the danger of prescribing opioids to treat chronic pain while simultaneously actively encouraging their utilization by exaggerating their benefits and generally characterizing the prescription of opioids as painkiller in a positive light. In other words, these ostensibly impartial KOLs and Front Groups carried out a PR campaign centered around the goal of increasing the prescription of opioids as much as possible.

75. As part of this campaign these organizations made false and misleading representations.

76. These representations were made at the implied or explicit direction of Defendants.

77. By availing themselves of unbranded advertising through third parties, Manufacturer Defendants were able to avoid regulatory scrutiny because such advertising is not submitted to and typically is not reviewed by the FDA.

78. Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source.

i. *Key Opinion Leaders (KOLs)*

79. Due to the highly technical nature of medicine, physicians must often rely on experts within certain fields of specialization to relay new discoveries to the rest of the profession. Doctors trust that these experts will faithfully report what new scientific research supports, and only what scientific research supports.

80. Key opinion leaders, or KOLs, are putative experts in a given field who wield a great amount of influence in their area of perceived expertise.

81. Defendants used KOLs by identifying doctors to serve, for payment, on Defendants' speakers' bureaus and to attend medical education programs as speakers.

82. In addition to compensation in the form of paid expenses and fees, doctors received professional recognition, making such speaking engagements desirable to physicians.

83. These speaker programs provided an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug) and to promote the drug through the speeches they asked to give (so that they might be engaged again in the future).

84. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting essentially a script prepared by Defendants.

85. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

86. In particular, Defendants used Dr. Russell Portenoy as a KOL to market their product and rebrand it within the medical community. Dr. Portenoy, the former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is

one of the names most associated with the meteoric surge in popularity of prescribing opioids to treat chronic pain. While evangelizing on behalf of Defendants' products, Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy's contributions to Defendants' cause include:

- a. Serving on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009
- b. Serving as a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Manufacturer Defendants
- c. Making frequent media appearances promoting opioids and spreading misrepresentations, including stating on Good Morning America in 2010 that "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."³⁸
- d. By his own admission, giving "innumerable lectures in the late 1980s and '90s about addiction that weren't true," claiming that fewer than 1% of patients would become addicted to opioids.³⁹

³⁸ Good Morning America (ABC television broadcast Aug. 30, 2010).

³⁹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

87. Dr. Portenoy, who has now retreated from his position in support of opioid and acknowledged its harm, has admitted that he was intentionally pursuing a campaign to destigmatize opioids, and that as a part of that campaign, he and other doctors promoting opioids, overstated their benefits and glossed over their risks. Dr. Portenoy now concedes that “[d]ata about the effectiveness of opioids does not exist.”⁴⁰

88. Defendants also used Dr. Lynn Webster as a KOL. Dr. Webster served as the President of American Academy of Pain Medicine (“AAPM”) in 2013 and as a Senior Editor of Pain Medicine, a journal used by Defendants for direct advertising.

89. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue and received significant funding from Manufacturer Defendants (including nearly \$2 million from Cephalon).

90. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster’s former patients at the Lifetree Clinic have died of opioid overdoses.

91. Dr. Webster is responsible for creating and promoting the “Opioid Risk Tool,” a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids.

92. But it is completely inadequate to provide any meaningful assistance in assessing tendency toward addiction.

⁴⁰ *Id.*

93. Versions of Dr. Webster’s superficial Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

94. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on Manufacturer Defendants and those under their influence and control.

95. Dr. Webster was a leading proponent of the concept of “pseudoaddiction,”⁴¹ – the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to increase a patient’s dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”⁴² Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”⁴³

96. In at least one instance Purdue sponsored a webinar in which Dr. Webster advised on the prescribing opioids to treat pain. This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff’s Community.⁴⁴

⁴¹ Though popularized by Dr. Portenoy, this concept was invented by a Purdue employee and is discussed further below.

⁴² Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

⁴³ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

⁴⁴ See Emerging Solutions in Pain, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

ii. *Front Groups*

97. Manufacturer Defendants entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturer Defendants, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy.

98. They also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturer Defendants.

99. Manufacturer Defendants contributed very large sums of money to these Front Groups, who in turn depended on the Manufacturer Defendants for funding and, in some cases, for survival. Furthermore, some of these Front Groups were led by industry-supported KOLs. Accordingly, Manufacturer Defendants were able to exercise great influence over these groups amounting to control, and in some cases perhaps even explicit control.

100. Manufacturer Defendants’ exercised their control over Front Groups’ programs, materials, and activity by “suggesting” activities and publications for the Front Groups to pursue; by collaborating on, editing, and approving their content; and by funding the dissemination of that content. In this way Manufacturer Defendants made sure that the Front Groups would generate the messages that the Manufacturer Defendants wanted to distribute and only those messages.

101. These messages touted the benefits of prescription opioids while trivializing their risks and were false and/or misleading.

102. One such Front Group, the American Academy of Pain Medicine (“AAPM”), began officially endorsing the use of opioids to treat chronic pain in 1996, claiming that the risk of a patient’s addiction to opioids was low. In 2009 it issued treatment guidelines in (“AAPM/APS Guidelines”) which recommended the use of opioids to treat chronic pain, characterizing them as “safe and effective” and stating the risk of addiction is manageable for patients regardless of past abuse histories.⁴⁵ One member of the panel which authored these guidelines resigned over concerns that they were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. Of the 21 panel members that remained, at least 14 received support from Janssen, Cephalon, Endo, and Purdue. Despite lacking evidentiary support, these guidelines were cited hundreds of times throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Furthermore, the AAPM/APS Guidelines were used by sales representatives employed by Endo, Actavis, and Purdue during individual sales visits to physicians. The Guidelines were disseminated in the State and/or Plaintiff’s Community during the relevant time period, are available online, and were reprinted in the Journal of Pain. All of this led to physicians, generally, and specifically those in Plaintiff’s state and/or community, relying on these misleading guidelines in making prescribing decisions regarding opioids.

103. The AAMP also sponsored and hosted medical education programs which were used to promote Defendants’ marketing message. These include dinner symposia held at resort locations where contributors of \$25,000 were allowed to present educational programs (these

⁴⁵ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

contributors were also given the opportunity to meet with AAPM executive committee members in small settings). The conferences placed a heavy emphasis on opioid “education,” with 37 of roughly 40 sessions at one conference focused on the topic. Additionally, AAPM maintained a close relationship with Defendant Endo which involved Endo funding AAPM CMEs and distributing AAPM publications. Given all of this, it comes as no surprise that leadership positions within the organization were held by industry-supported KOLs, including a president who was under DEA investigation at the time of his election.

104. Some Front Groups, such as the Pain Care Forum (“PCF”), were comprised almost entirely of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Manufacturer Defendants. Among other projects, the PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Manufacturer Defendants determined would reduce prescribing.

105. In addition to the organizations already mentioned, Defendants funded and exercised some degree over the American Pain Foundation (“APF”), the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and Pain & Policy Studies Group (“PPSG”), and possibly others.⁴⁶

⁴⁶ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015), <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

106. While engaged in the type of activity described above, and thus serving the interests of Manufacturer Defendants, the Front Groups held themselves out as independent and serving the interests of those whom they targeted – whether patients suffering from pain or doctors treating those patients.

2. Manufacturing Defendants’ Misleading Marketing

107. Manufacturing Defendants and those acting on their behalf made and/or published dozens of false and/or misleading representations through affirmative statements and deceptive omissions with the purpose and effect of increasing sales of their prescription opioid products at the expense of the consumers of those products, including those in Plaintiff’s community.

i. *Manufacturer Defendants Concealed or Deceptively Understated the Danger of Opioids.*

108. Many of these misrepresentations were specifically designed to conceal the danger of Defendants’ products and encourage unsafe use of prescription opioids, including 1) misstating the risk of addiction to prescription opioids, 2) inventing and promoting the false concept of “pseudoaddiction” to prevent physicians from recognizing that a patient is addicted to opioids, 3) falsely stating that certain tools were effective to detect addiction, creating a false sense of confidence in prescribers, 4) falsely stating that dependence can be easily reversed, 4) falsely stating that prescribers could increase the dosage of opioids without increasing the risk of addiction, and 5) falsely stating that abuse-deterrent features in their products would effectively prevent certain kinds of abuse.

109. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” and that “continuing opioid therapy for 3 months substantially

increases risk for opioid use disorder.”⁴⁷ Furthermore, these risks are established by “*extensive* evidence.”⁴⁸

110. Despite these risks Manufacturing Defendants falsely presented their prescription opioid products as safe.

111. They had no reason to think this was the case and knew it was not. Their misrepresentations were intentionally deceptive.

112. Specific examples of the ways in which Defendants misstated the risk of their products include but are not limited to:

- a. Actavis’s predecessor (former owner of Kadian, see paragraph 33) caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is “less likely if you have never had an addiction problem.” Based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond;
- b. Cephalon and Purdue sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid

⁴⁷ 2016 CDC Guideline, *supra* note 33 at 2, 25.

⁴⁸ *Id.* at 15 (emphasis added).

prescriptions from multiple sources, or theft. This publication is still available online;⁴⁹

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications;
- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem;”
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain;”

⁴⁹ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

- f. Janssen currently runs a website, Prescriberresponsibly.com (last accessed April 30, 2018), which claims that concerns about opioid addiction are “overestimated;”
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction;”⁵⁰
- h. Consistent with Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiff’s Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above;
- i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, Manufacturer Defendants’ Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.⁵¹

113. One of Purdue’s employees, Dr. David Haddox, invented a phenomenon called “pseudoaddiction,” which was then popularized by KOL, Dr. Portenoy. This is the false idea that

⁵⁰ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

⁵¹ Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

certain indicators of addiction in patients on opioids are not actually indicative of addiction but rather of *undermedication*.⁵² This concept is doubly insidious as it not only prevents doctors from identifying addiction in patients but actually encourages them to give *more* pills to those most at risk.

114. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

- a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.⁵³ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real;⁵⁴
- b. Janssen sponsored, funded, and edited the Let’s Talk Pain website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management;”
- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which, upon information and belief, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo

⁵² 2016 CDC Guideline, *supra* note 33

⁵³ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2007) at 62.

⁵⁴ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

- appears to have substantially controlled NIPC by funding NIPC projects;
developing, specifying, and reviewing content; and distributing NIPC materials;
- d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated;” and
- e. Upon information and belief, Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse”. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid;

115. Despite the fact that there existed no study assessing the effectiveness of addiction risk screening tools, Manufacturing Defendants presented them to physicians as reliable and clothed in the authority of the product’s maker.⁵⁵

116. Manufacturing Defendants specifically targeted misleading messages concerning the effectiveness of certain screening tools toward general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids and are thus more

⁵⁵ *Id.* at 11.

susceptible to false information. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts;
- b. Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;"
- c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

117. Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use.

118. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings,

anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.⁵⁶ Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled “Persistent Pain in the Older Adult,” claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. And Purdue sponsored APF’s A Policymaker’s Guide to Understanding Pain & Its Management, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.⁵⁷

119. Manufacturer Defendants claimed that opioid dosages could be increased indefinitely without added risk.

120. This is patently false. According to the CDC, “[b]enefits of high-dose opioids for chronic pain are not established” while “the risks for serious harms related to opioid therapy, increase at higher opioid dosage,” including risk of opioid use disorder, overdose, and death.⁵⁸

121. The ability to escalate dosages was critical to Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief.

122. These misrepresentations led to the prescription of dangerously high dosages of opioids across the country, including in Plaintiff’s community, causing great harm.

123. Manufacturer Defendants’ deceptive dosage claims include:

⁵⁶ *Id.* at 26.

⁵⁷ APF, Policymaker’s Guide, *supra*, note 47.

⁵⁸ 2016 CDC Guideline, *supra* note 33, at 21–24.

- a. Upon information and belief, Actavis's predecessor (see paragraph 33) created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond;
- b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.⁵⁹ This publication is still available online;
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain;"
- d. Endo distributed a pamphlet edited by a KOL entitled Understanding Your Pain: Taking Oral Opioid Analgesics (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief;"⁶⁰

⁵⁹ APF, Treatment Options, *supra*, note 46.

⁶⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

- e. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased opioid dosages;
- f. Upon information and belief, Purdue’s in the Face of Pain website promoted the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF’s A Policymaker’s Guide to Understanding Pain & Its Management, which taught that dosage escalations are “sometimes necessary,” and that “the need for higher doses of medication is not necessarily indicative of addiction,” but inaccurately downplayed the risks from high opioid dosages;⁶¹
- h. In 2007, Purdue sponsored a CME entitled “Overview of Management Options” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages;
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose;⁶² and

⁶¹ APF, Policymaker’s Guide, *supra*, note 47.

⁶² The College on Problems of Drug Dependence, About the College, <http://cpdd.org> (last visited Aug. 21, 2017).

- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, Manufacturer Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.⁶³

124. Defendants' deceptive marketing of the so-called "abuse-deterrent" properties of some of their opioids has created false impressions that these opioids can prevent abuse.

125. Manufacturer Defendants made misleading claims about the ability of their abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false.

126. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets "can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."⁶⁴ Similarly, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."⁶⁵ The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."⁶⁶ Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

127. In June 2017, the FDA requested that Opana ER be removed from the market.

⁶³ Brief of APF, *supra*, note 48.

⁶⁴ Letter from Janet Woodcock, M.D., Dir., Centers For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

⁶⁵ *Id.* at 6.

⁶⁶ *Id.* at 6, n. 21.

128. Prescribers relied on Manufacturer Defendants misrepresentations about the safety of abuse-deterrent products causing them to let down their guard and prescribe opioids to those they would not have absent Defendants' misrepresentations.

ii. *Manufacturer Defendants Deceptively Overstated the Benefits of Prescription Opioid Products.*

129. The CDC has made clear that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.⁶⁷ The FDA, too, has recognized the lack of evidence to support long-term opioid use.

130. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

131. This was no accident. The driving force behind the exponential growth of the prescription opioid market was the extension of their application to chronic pain, whereas before they had (correctly) been deemed inappropriate for such treatment.

132. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose.

133. In fact, OxyContin does not last for 12 hours – something that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more

⁶⁷ *Id.* at 15.

than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers.

134. This front-loading of effect results in a powerful initial response but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

135. Upon information and belief, Endo ran advertisements for Opana ER referring to “real” 12-hour dosing, indicating that there was a general knowledge within the industry that OxyContin does not provide 12-hour relief, in which case Purdue would have certainly been aware of the falseness of such claims.

136. Upon information and belief, Purdue’s sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

137. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient

sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.⁶⁸

138. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.⁶⁹ Specifically, the FDA advised that Fentora “is only approved for breakthrough cancer pain in patients who are opioid-tolerant, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication.”⁷⁰

139. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used

⁶⁸ Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

⁶⁹ See U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

⁷⁰ *Id.*

CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain;
- b. Upon information and belief, Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

140. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain but were also approved by the FDA for such uses.

141. Other examples of Manufacturer Defendants’ false claims include:

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives;
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;
- c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;
- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors’ offices, of presumed patients in active professions; the caption read, “Pain doesn’t fit into their schedules;”
- e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients’ function;
- f. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function;

- g. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."⁷¹ This publication is still available online;
- h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site;
- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."⁷² Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning;"
- j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function;"

⁷¹ APF, Treatment Options, *supra*, note 39.

⁷² *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007).

- k. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."⁷³ The Policymaker's Guide was originally published in 2011; and
- l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

142. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

iii. *Manufacturer Defendants Maligned Competing Forms of Pain Relief Medications.*

143. The FDA and CDC have both said that NSAIDs should be the first-line treatment for chronic pain, particularly arthritis and lower back pain, and that opioids should only be resorted to after other options have been exhausted.⁷⁴

144. Manufacturer Defendants falsely and misleadingly emphasized or exaggerated the risks of competing medications like non-steroidal anti-inflammatory drugs (NSAIDs), so that doctors and patients would look to opioids first for the treatment of chronic pain.

iv. *Enumerations of Individual Defendants' Known and Reasonably Suspected Tortious Activity*

145. As alleged herein, Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of

⁷³ APF, Policymaker's Guide, *supra*, note 47.

⁷⁴ 2016 CDC Guideline, *supra* note 33, at 12.

manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

146. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including

known rates of abuse and addiction and the lack of validation for long-term efficacy;

- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

147. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

148. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

149. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

150. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

151. Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive.

C. Defendants' Failure to Guard Against Opioid Diversion

152. Defendants owe a duty under both federal law and Georgia law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

153. Defendants repeatedly and purposefully breached their duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

154. Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid crisis and causing the harms and damages alleged herein.

1. Distributor Defendants' Duty to Guard Against Opioid Diversion

155. Opioids are classified as a Schedule II controlled substance, a classification reserved for the prescription drugs that present the greatest risk to public health due to their potential for abuse.⁷⁵

156. As wholesale drug distributors, each Distributor Defendant was required under Georgia law to obtain a license as a wholesaler of controlled substances.⁷⁶ Each Distributor

⁷⁵ O.C.G.A. § 16-13-71; 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

⁷⁶ O.C.G.A. § 26-4-115.

Defendant is licensed by the Georgia Board of Pharmacy and is a “registrant” or “licensee” as a wholesale distributor in the chain of distribution of Schedule II controlled substances

157. As registrants, Distributor Defendants assumed a duty under Georgia state law to comply with all security requirements imposed under the regulations adopted by the Georgia Board of Pharmacy.

158. Georgia law requires that drug wholesalers “maintain records of unusual orders of controlled substances received by the registrant and shall inform the Office of the Director of the Georgia Drugs and Narcotics Agency (GDNA) of unusual orders when discovered by the registrant.”⁷⁷

159. Each Distributor Defendant was also required to register with the DEA, pursuant to the federal Controlled Substance Act.⁷⁸ Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances.

160. As a registrant, each Distributor Defendant has a duty under federal law to comply with all security requirements imposed under that statutory scheme.

161. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”⁷⁹

162. Accordingly, each Distributor Defendant has, and at all relevant times had, an affirmative duty under both Georgia and federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs.

⁷⁷ O.C.G.A. § 26-4-115(b)(2); Ga. Comp. R. & Regs. r. 480-20.02.

⁷⁸ 21 U.S.C. § 823(b), (e); 28 C.F.R. §0.100.

⁷⁹ 21 U.S.C. §§ 823(b)(1).

163. Federal regulations impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”⁸⁰

164. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern.⁸¹ These criteria are disjunctive and are not exhaustive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

165. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially

⁸⁰ 21 C.F.R. § 1301.74(b).

⁸¹ 21 C.F.R. 1301.74(b); Ga. Comp. R. & Regs. r. 480-20-.02(1).

suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.⁸² Regardless, all flagged orders must be reported.⁸³

166. This regulatory scheme relies on registrant distributors to perform these duties in order to create a “closed” system. Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁸⁴

167. Without distributor cooperation, there is a hole in the closed system which causes it to fall apart. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”⁸⁵

168. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from

⁸² *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).

⁸³ *Id.*

⁸⁴ *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

⁸⁵ *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.⁸⁶

169. Distributor Defendants have admitted not only that they are responsible specifically for reporting suspicious orders, but that they have general “statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs but undertake such efforts as responsible members of society.”⁸⁷

170. Though Distributor defendants have denied that they have duties beyond reporting suspicious order, the Court of Appeals for the District of Columbia has held otherwise.⁸⁸

171. Distributor Defendants also had a responsibility to monitor, detect, and halt suspicious orders, which they were aware of.

172. In 2006 the DEA advised each Distributor Defendant in writing that a distributor, in addition to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”⁸⁹ They stated “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful

⁸⁶ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

⁸⁷ See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *2, *4.

⁸⁸ *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

⁸⁹ Rannazzisi Letter, *supra*, note 82

purposes.”⁹⁰ The DEA warned Distributor Defendants that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”⁹¹

173. The following year the DEA sent a second letter to each Distributor Defendant.⁹² This letter detailed specific tasks that distributors must perform as part of their duty to guard against diversion and provided guidelines on how to perform them, including criteria for determining whether an order is suspicious.⁹³ It also clearly stated that failure to perform those duties is a violation of the law.

174. Furthermore, the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, established industry compliance guidelines, which explained that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.⁹⁴

⁹⁰ *Id.* at 1.

⁹¹ *Id.* at 2.

⁹² See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv- 00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

⁹³ *Id.*

⁹⁴ Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

175. Accordingly, each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

176. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

177. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

178. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

179. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

180. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

2. Distributor Defendants' Breach of Duty

181. Each Distributor Defendant sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

182. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community, is excessive for the medical need of the

community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.⁹⁵

183. Distributor Defendants failed to report “suspicious orders” originating from Plaintiff’s Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff’s Community, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

184. Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff’s Community, and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Plaintiff’s Community.

185. Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff’s Community, and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Plaintiff’s Community.

186. Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

187. Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the

⁹⁵ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

188. Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.⁹⁶

189. The federal and state laws at issue here are public safety laws.

190. Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

191. Distributor Defendants' unlawful conduct is purposeful and intentional.

192. Distributor Defendants actively refuse to abide by their federal and state law duties, which were imposed as a condition for being granted a position of public trust giving them the privilege to deal in dangerous and otherwise prohibited material.

193. Distributor Defendants not only violated that trust by failing to detect and prevent opioid diversion, they treated the public trust with contempt by failing to even try.

194. In so doing, Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

195. Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal

⁹⁶ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

196. Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding Distributor Defendants' compliance with their legal duties.

197. In 2017 wholesale Distributor McKesson admitted that it failed repeatedly to perform its statutory duties during the period from 2009 to 2017. Specifically, it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."⁹⁷ Further, McKesson has admitted it "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies were not properly dispensing controlled substances, as required by 21 C.F.R. § 1306.04(a)."⁹⁸ During this time period, McKesson "failed to maintain effective controls against [illegal] diversion of particular controlled substances . . . in violation of the CSA and the CSA's implementing regulations."⁹⁹

198. These 2017 admissions followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.¹⁰⁰ In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all

⁹⁷ See Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

⁹⁸ *Id.* at 4.

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 4.

controlled substances and report suspicious orders to DEA,” but had failed to do so.¹⁰¹ The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.”¹⁰² As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.¹⁰³

199. As a result of Distributor Defendants’ refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance.

200. Quite apart from instance of *suspected* distributor wrong-doing, the Office of Administrative Law Judges found ground for *immediate suspension* of DEA registration in 41 cases between 2008 and 2012 alone.¹⁰⁴

201. Examples of such suspension include the following:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

¹⁰¹ *Id.*

¹⁰² *Id.*; *see also*, Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) (“McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.”), <https://www.justice.gov/opa/press-release/file/928471/download>.

¹⁰³ *Id.* at 6.

¹⁰⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, The Drug Enforcement Administration’s Adjudication of Registrant Actions 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;

- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

202. Rather than abide by the public safety laws and carry out their non-delegable duties established thereunder, Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.¹⁰⁵

203. In addition to taking actions to limit regulatory prosecutions and suspensions, Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

204. By misleading the public about the effectiveness of their controlled substance monitoring programs, Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the

¹⁰⁵ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, CHARLESTON GAZ.-MAIL, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

205. While Distributor Defendants sparred with the DEA, the opioid epidemic continued and still continues to rage unabated in the Nation, the State, and in Plaintiff's Community.

206. This is due in part to the fact that the fines and suspensions imposed by the DEA do not change the conduct of the industry because they are outweighed by the profit of the behavior which they fail to curb. The distributors, including Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

207. The wrongful actions and omissions of Distributor Defendants have caused the diversion of opioids, substantially contributing to the disturbingly high availability of powerful narcotics, which in turn gave rise to the opioid crisis.

208. Distributor Defendants breach of their duty to the public generally, and to members of Plaintiff's community specifically, is a proximate cause of the opioid crisis.

3. Manufacturer Defendants' Duty to Guard Against Opioid Diversion

209. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon Distributor Defendants were also legally required of Manufacturer Defendants under federal law.

210. Like Distributor Defendants, Manufacturer Defendants were required to register with the DEA to manufacture Schedule II controlled substances, like prescription opioids.¹⁰⁶

¹⁰⁶ 21 U.S.C. § 823(a).

211. A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes...¹⁰⁷

212. Additionally, as “registrants” under Section 823, Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.¹⁰⁸

213. Like Distributor Defendants, the Manufacturer Defendants breached these duties.

214. Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion.

215. Manufacturer Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus,

¹⁰⁷ 21 USCA § 823(a)(1) (emphasis added).

¹⁰⁸ 21 C.F.R. § 1301.74.; *see also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).”).

Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

216. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.”¹⁰⁹

217. The duty of manufacturers to report suspicious orders was recently confirmed when Mallinckrodt paid \$35 million in fines as part of settlement agreement resulting from failure to report suspicious orders of controlled substances recordkeeping violations.¹¹⁰

218. Among the allegations resolved by the settlement, were the governments claims that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns” and that “Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, with an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”¹¹¹

¹⁰⁹ 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

¹¹⁰ Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

¹¹¹ *Id.*

219. Mallinckrodt conceded that it has a responsibility to maintain effective controls against diversion, and that it is required to review and monitor sales and report suspicious orders to DEA.¹¹²

220. The settlement agreement identified the following duties of an opioid manufacturer that Mallinckrodt failed to fulfill:

- a. Conduct adequate due diligence of its customers;
- b. Detect and report to the DEA orders of unusual size and frequency;
- c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 - i. Orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 - ii. Orders that purchased a disproportionate amount of a substance which is most often abused compared to other products; and
 - iii. Orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- d. Use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain

¹¹² Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, PLC. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download..>

discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

- e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.¹¹³

221. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”¹¹⁴

222. Federal law imposes the same duty on all other Manufacturer Defendants that it does on Mallinckrodt.

223. The same business practices utilized by Mallinckrodt regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

224. Through chargeback data and other similar types of information available to them, Manufacturer Defendants could monitor suspicious orders of opioids and had a statutory duty to do so.

4. Manufacturer Defendants’ Breach

¹¹³ *Id.* at 2-3.

¹¹⁴ *Id.* at 5.

225. The Manufacturer Defendants repeatedly failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

226. Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

227. This constitutes a purposeful breach of Manufacturer Defendants' duties under state and federal law.

228. Manufacturer Defendants have misrepresented their compliance with federal law.

229. Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

230. The wrongful actions and omissions of Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

231. As with Distributor Defendants, this diversion resulted in highly available narcotics, and this availability caused the opioid crisis.

232. Accordingly Manufacturer Defendants' failure to fulfill its duties to prevent diversion of prescription opioids was a proximate cause of the opioid crisis and Plaintiffs' associated damages.

V. DAMAGES

233. Defendants intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein.

234. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

235. Plaintiff seeks economic damages from Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

236. Plaintiff seeks economic damages from Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

237. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."¹¹⁵

238. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.¹¹⁶

239. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."¹¹⁷

240. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

VI. STATUTE OF LIMITATIONS

¹¹⁵ Rudd et al., *supra*, note 28 at 1145.

¹¹⁶ Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

¹¹⁷ Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

241. Plaintiff contends it continues to suffer harm from Defendants' unlawful actions.

242. The continued tortious and unlawful conduct of Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

243. Furthermore, Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

244. Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

245. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

246. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

247. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein.

248. Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's Community. Plaintiff did not know or could not have known through the exercise of reasonable diligence, of its cause of action, because of Defendants' conduct.

249. Defendants' fraudulent misrepresentations, suppressions, and concealments or material facts also constitute a fraudulent concealment from Plaintiff of the existence of causes of action by which Plaintiff could have sought recovery from Defendants for Plaintiff's injuries suffered because of Defendants' wrongful conduct.

250. As a proximate result of Defendants' fraudulent misrepresentations, suppressions, and concealments Plaintiffs have been, and continue to be, injured and have incurred damages as stated herein.

251. As such, the limitations period has been tolled, and Plaintiff has brought this action upon discovering the existence of the facts underlying the causes of action alleged herein, within the limitations period.¹¹⁸

LEGAL CAUSES OF ACTION

COUNT I PUBLIC NUISANCE (Against all Defendants)

¹¹⁸ O.C.G.A. § 9-3-96.

252. Plaintiff incorporates by reference all preceding paragraphs.

253. A nuisance is “anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it from being a nuisance.”¹¹⁹

254. Under Georgia law, a “public nuisance” is “one which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals.”¹²⁰ It is sufficient if it injures those of the public who may actually come in contact with it.¹²¹

255. Significant interference with “the public health, the public safety, the public peace, the public comfort or the public convenience” may support a finding of public nuisance. For example, . . . the illegal dealing of drugs . . . constituted ample evidence of a public nuisance.¹²²

256. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in the City of Dawson for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use. This includes both illegal use of prescription opioids for which Defendants are directly responsible and the dramatic increase in inherently illicit opioids, such as heroin, which was the foreseeable, natural, and proximate result of the wrongful promotion and distribution of dangerous narcotics in service of the expansion of their massive drug selling operations.

257. The opioid crisis forming the basis of this action is so pervasive and so massive in scale, that it negatively affects Plaintiff’s entire community, whether directly through contact with opioids, or indirectly through greater apprehension of crime, costs of subsidizing support of

¹¹⁹ O.C.G.A. § 41-1-1.

¹²⁰ O.C.G.A. § 41-1-2.

¹²¹ *Atlanta Processing Co. v. Brown*, 227 Ga. 203, 211, 179 S.E.2d 752, 758 (1971).

¹²² *City of College Park v. 2600 Camp Creek, LLC*, 666 S.E.2d (Ga. Ct. App. 2008).

those affected directly, and lost contributions from those affected. Accordingly it affects rights which are common to all within the community.

258. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of the City of Dawson and the surrounding areas.

259. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to the City of Dawson and its residents.

260. Defendants knew or should have known that their actions promoted unsafe opioid use and that this promotion would lead to addiction and other adverse consequences, creating a public nuisance.

261. Manufacturer Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs.

262. This resulted in a major shift in how doctors prescribe opioids, expanding the generally accepted use to treatment of chronic pain, which caused a *drastic* increase in the use and availability of prescription opioids, the scale of which is staggering.

263. Defendants' disregard for diversion prevention and breach of their related statutory duties led to widespread illegal possession and abuse of prescription opioids.

264. Furthermore, Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including so-called "pill mills" and other dealers.

265. Defendants' failure to implement effective controls and procedures in their supply chains to guard against diversion was a substantial factor in opioids becoming widely available

and widely abused and was particularly important in facilitating strictly illicit prescription opioid transactions

266. Because of the dangerous and addictive nature of opioids and the high substitutability between prescription opioids and illicit opioids such as heroin, the spike in use and availability of prescription opioids caused by Defendants' actions directly caused the opioid crisis herein complained of.

267. The public nuisance created by Defendants endangers the health and safety of the City of Dawson and its residents.

268. The public nuisance created by Defendants has caused, and continues to cause, significant harm to, and the expenditure of taxpayer dollars by Plaintiff including, but not limited to the following:

- a. The unprecedented rates of opioid use among adults in the City of Dawson has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in the City of Dawson.
- b. Infants have been born addicted to opioids due to pre-natal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for illicit use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.
- d. The diversion of opioids into the secondary, illicit market and the increase in the number of individuals who abuse or are addicted to opioids has placed

unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of the City of Dawson.

- e. Adults and children in the City of Dawson who have never taken opioids have also suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. All these problems harm Plaintiff by diminishing its revenues and forcing it to make increased expenditures.

269. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in Defendants' failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Defendants' dissemination of false "scientific" facts and advice.

270. At all times, Defendants possessed the right and ability to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale into the City of Dawson. Defendants had the power to shut off the supply of illicit opioids into the City. Defendants had the power to stop providing false information and warn the public about the dangers of opioids and the highly addictive nature of their opioid products. Therefore each Defendant is the cause, or a concurrent cause, of the creation, continuance, and maintenance of the nuisance.

271. This public nuisance is a continuing nuisance but not a permanent one because it can and should be abated.¹²³ Indeed, it must be.

272. As a direct and proximate result of the public nuisance, Plaintiff has sustained harm by spending a substantial amount of money trying to fix the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, judicial services, incarceration, medical examinations, burials, and law enforcement.

273. Plaintiff's public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the public at large in the City of Dawson.

274. Plaintiff will be required to further expend great sums of money to abate the nuisance by, among other things, implementing comprehensive public programs to address the opioid crisis and rectify the harm caused by Defendants.

275. Defendants should be required to pay the expenses the Plaintiff has incurred and will incur in the future to fully abate the nuisance.

276. Defendants' conscious indifference to the shocking consequences of their actions merits an award of punitive damages.¹²⁴

COUNT II
NEGLIGENCE
(Against all Defendants)

277. Plaintiff incorporates by reference all preceding paragraphs.

¹²³ *City of Atlanta v. Kleber*, 285 Ga. 413, 416, 677 S.E.2d 134, 137 (2009) (citation omitted).

¹²⁴ *In re Flyboy Aviation Properties, LLC*, 525 B.R. 510, 527–28 (Bankr. N.D. Ga. 2015).

278. The elements of negligence under Georgia law are that a defendant had “a legal duty; breached that duty; a causal connection exists between the defendant’s conduct and the plaintiff’s injury; and the plaintiff suffered damages.”¹²⁵

279. Each Defendant had an obligation and duty to exercise reasonable care in the manufacturing, marketing, and distribution of highly dangerous opioid drugs in and around the City of Dawson.

280. The injuries and harms to the City were foreseeable and in fact were foreseen by each Defendant.

281. Therefore each Defendant owed a duty to Plaintiff, and to the public health and safety in the City of Dawson, to avoid causing that harm.

282. Defendants breached this duty by failing to take any action to prevent or reduce the improper distribution and illegal diversion of the opioid drugs.

283. Manufacturer Defendants also breached this duty by engaging in misleading marketing operations designed to increase sales of their opioid products without regard to the safety of the consumers of those products.

284. Reasonably prudent wholesale drug manufactures, marketers, and distributors would have anticipated the scourge of opioid addiction that would wreak havoc on communities, including Plaintiff’s especially if repeatedly warned by law enforcement as Defendants were.

285. The sheer volume of addictive drugs flowing through Defendants’ businesses should have made obvious to Defendants that addiction was fueling the increased consumption and that

¹²⁵ See, e.g., *Seymour Elec. and Air Conditioning Service, Inc. v. Statom*, 710 S.E.2d 677, 679 (Ga. Ct. App 2011).

legitimate medical purposes were not being served, especially when compared to the number of people who lived in the areas where the drugs were being shipped.

286. In the very least, these circumstances would lead any reasonable dealer of pharmaceutical narcotics to both investigate such a possibility and develop sophisticated security measures to prevent illegal diversion.

287. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

288. Defendants were negligent in not disclosing to Plaintiff and/or the proper authorities suspicious orders for opioids pursuant to the requirements of the Controlled Substances Act as well as Georgia State law.

289. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

290. Defendants are in a class of a limited number of parties that can legally manufacture and distribute opioids, which places it in a position of great trust by Plaintiff.

291. State and federal regulators have invested Defendants with the trust of the public by granting them license to manufacture opioids and distribute them in the City of Dawson and throughout Georgia. In exchange for this license, Defendants took on a duty, to the public generally and to Plaintiff's community specifically, to prevent the illegal diversion of the dangerous medications in which it is permitted to deal.

292. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to Plaintiff and its residents from the diversion of opioids for non- legitimate medical purposes and addiction to the same by consumers.

293. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

294. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during manufacture and distribution.

295. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

296. Manufacturing Defendants marketed opioids in an improper manner by overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use; trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death; overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

297. It was Manufacturing Defendants' marketing, not any medical breakthrough, which rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

298. Manufacturing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, sponsoring KOLs and Front Groups, and

publishing their unsupported conclusions concerning opioids, and even collaborated on these materials, encouraging the dissemination of unsupported claims.

299. Manufacturing Defendants knew or should have known that these claims were unsupported at best.

300. Manufacturing Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause addiction.

301. Manufacturing Defendants' marketing was a factor in physicians, patients, and others to prescribe or purchase opioids.

302. Manufacturing Defendants knew or should have known that their conduct would lead to unsafe prescription and use of opioids.

303. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for Plaintiff's residents and using Plaintiff's resources in relation to opioid use and abuse.

304. Defendants are in exclusive control of the management of the opioids they manufacture, market, and distribute in the City of Dawson.

305. Plaintiff is without fault and the injuries to the City and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture and distribution of opioids.

306. Plaintiff is entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

COUNT III
NEGLIGENCE PER SE
(Against All Defendants)

307. Plaintiff incorporates by reference all preceding paragraphs.

308. “A plaintiff may assert a claim of negligence *per se* arising from violations of federal or state statutes as long as (1) that plaintiff falls within the class of persons the statute was intended to protect; (2) the harm complained of was the same harm the statute was intended to guard against; and (3) the violation of the statute proximately caused the plaintiff’s injury.”¹²⁶

309. Each Defendant had a duty under federal and state law to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.

310. Performance of these statutory duties is mandatory, and this requirement has the full force of law.

311. These laws are intended to protect the health, safety, and welfare of individuals and communities, such as Plaintiff’s, from the deleterious effects of dangerous drugs by preventing their diversion.¹²⁷

312. In violation of these laws, Defendants intentionally distributed and/or sold dangerous controlled substances without performing these required duties.

313. This violation increased the likelihood of, actually resulted in, and continues to result in, the diversion of prescription opioids, which is the activity the above-referenced federal and state laws seek to prevent.

¹²⁶ *McLain v. Mariner Health Care, Inc.*, 279 Ga. App. 410, 411, 631 S.E.2d 435, 437 (2006).

¹²⁷ 21 U.S.C.A. § 801; O.C.G.A. § 26-4-2.

314. That diversion proximately caused the opioid crisis which is the source of the injuries here complained of.

315. Defendants' actions and omissions in violation of the law constitute actionable negligence *per se*.

316. Defendants' illegal activity caused damages to Plaintiff including, but not limited to, the costs of caring for those who need support due to opioid addiction or overdose, the medical expenses incurred by Plaintiff associated with illicit opioid use, the cost of treatment programs for those addicted to opioids, costs of increased law enforcement utilization, and the cost of education programs to counter the increased social pressure on young people to abuse opioids.

317. Defendants are liable for the cost of all Plaintiff's damages including those just listed, other past damages already incurred as a result of Defendants actions, and all future damages that will likely occur as a result of those actions.

318. Plaintiff seeks to recover the cost of all such damages resulting from Defendants' negligence *per se*.

319. Plaintiff seeks all legal and equitable relief as allowed by law.

COUNT IV
CLAIM FOR DAMAGES FOR VIOLATION OF LEGAL DUTY
(Against Distributor Defendants)

320. Plaintiff incorporates by reference all preceding paragraphs.

321. Section 51-1-6 of the Georgia Code provides for recovery of damages suffered as the result of a breach of duty created by law.

322. Each Defendant had a duty under federal and state law to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.¹²⁸

323. Performance of these statutory duties is mandatory, and this requirement has the full force of law.

324. These laws are intended to protect the health, safety, and welfare of individuals and communities, such as Plaintiff's, from the deleterious effects of dangerous drugs by preventing their diversion.¹²⁹ Thus they were enacted for Plaintiff's benefit.

325. In violation of these laws, Defendants intentionally distributed and/or sold dangerous controlled substances without performing these required duties.

326. Defendants' violations of these laws breached a legal duty to Plaintiff created by the laws.

327. This breach resulted in the type of harm the laws seek to prevent, namely the diversion, illegal sale, and illegal use of dangerous drugs, which caused injury to Plaintiff and Plaintiff's Community.

328. Under O.C.G.A. § 51-1-6, Plaintiff is entitled to recover damages for caused by Defendants' breach of their legal duty to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.

329. Plaintiff seeks to recover the cost of all such damages resulting from Defendants' negligence *per se*.

330. Plaintiff seeks all legal and equitable relief as allowed by law.

¹²⁸ 21 U.S.C. § 823; 21 CFR 1301.74; O.C.G.A. § 26-4-115.

¹²⁹ 21 U.S.C.A. § 801; O.C.G.A. § 26-4-2.

COUNT V
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (RICO)
(18 U.S.C. §1961, et. seq.)
(Against All Defendants)

331. Plaintiff incorporates by reference all preceding paragraphs.

332. Defendants conducted the affairs of the enterprises described below through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

333. Defendants are persons within the meaning of 18 U.S.C. §1961(3).

334. Section 1962(c) of the Racketeer Influenced and Corrupt Organizations Act (RICO) makes it unlawful “for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.”¹³⁰

A. Relevant Enterprises

335. The definition of the term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”¹³¹ This definition encompasses both legitimate and illegitimate enterprises.

336. Defendants engaged in two relevant illegal enterprises in violation of these statutes: the Opioid Promotion Enterprise and the Opioid Diversion Enterprise.

337. The Opioid Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Manufacturer Defendants, including their employees and agents;

¹³⁰ 18 U.S.C. §1962(c).

¹³¹ 18 U.S.C. § 1961(4).

Front Groups, including their employees and agents; and KOL's; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. §1961(3) and acted to enable Manufacturing Defendants to fraudulently market opioids as scientifically-proven to be safe and effective. The Opioid Promotion Enterprise functioned as an ongoing organization and continuing unit and was separate and distinct from 1) each of its component entities and 2) from the pattern of racketeering activity carried out by those entities. The Opioid Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity and maintained systematic links through corporate ties, contractual relationships, interrelated financial interests, and continuing coordination of activities for a common purpose: to ensure the prescription of opioids for chronic pain. The Manufacturing Defendants participated in the operation and management of the opioid marketing fraud enterprise by directing its affairs. Each member of the Opioid Promotion Enterprise shared in the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers in Plaintiff's community.

338. The Opioid Diversion Enterprise is an association-in-fact between Manufacturer Defendants and Distributor Defendants and executed by each of them. In particular, each Defendant was associated with, and conducted or participated in, the affairs of the enterprise, whose purpose was to engage in the unlawful sales of opioids and to deceive the public and regulators into believing that Defendants were faithfully fulfilling their statutory obligations.

339. Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully

increasing revenues, profits, and market share. As a direct result of Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Plaintiff suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, Defendants' misconduct violated Section 1962(c), and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

340. Members of the Opioid Diversion Enterprise, finding it impossible to legally achieve their ever-increasing sales ambitions, systematically and fraudulently violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.¹³² As discussed in detail below, through Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.¹³³ In doing so, Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

341. Alternatively, Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (HDA) is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, the HDA qualifies as an

¹³² 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

¹³³ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

“enterprise” within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

342. On information and belief, Defendants are members, participants, and/or sponsors of the HDA and utilized it to conduct the Opioid Diversion RICO Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

343. Each Defendant is a legal entity separate and distinct from the HDA, and the HDA serves the interests of distributors and manufacturers beyond Defendants.

344. The HDA exists separately from the Opioid Diversion Enterprise, and each Defendant exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

345. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the legal enterprise (HDA) were each used by Defendants to conduct the RICO Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the “RICO Enterprise.”

346. Each Defendant qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant.¹³⁴

¹³⁴ 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

347. Pursuant to the CSA and the Code of Federal Regulations, Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

348. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

349. At all relevant times, Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

350. At all relevant times, the RICO Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each Defendants; (d) characterized by interpersonal relationships among Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and

then requesting the DEA increase production quotas, all so that Defendants would have a larger pool of prescription opioids from which to profit.

351. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold Defendants liable for disregarding their duty to prevent diversion.

352. Members of the Pain Care Forum (PCF) and HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. PCF and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

353. The RICO Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But Defendants' profits were limited by the production quotas set by the DEA, so Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high

production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

354. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the City and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

355. Within the RICO Enterprise, there were interpersonal relationships and common communication by which Defendants shared information on a regular basis.

356. These interpersonal relationships also formed the organization of the RICO Enterprise. The RICO Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

357. Each Defendant had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. Defendants participated in the operation and management of the RICO Enterprise by directing its affairs, as described herein.

358. While Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

359. Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the PCF and HDA, and through their contractual relationships.

360. The PCF has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national

news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

361. The Center for Public Integrity and the Associated Press obtained “internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.” Specifically, PCF participants spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.

362. Not surprisingly, each Defendant who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in PCF. In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Johnson & Johnson, Allergan, and Teva. Each Manufacturer Defendant worked together through the PCF to advance the interests of the enterprise. But Manufacturer Defendants were not alone. Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.

363. The 2012 PCF Meeting Schedule indicates that meetings were generally held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis. Local members were encouraged to attend the monthly meetings in person, suggesting interpersonal relationships among the members and their representatives.

364. The 2012 PCF Meeting Schedule demonstrates that each Defendant participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug-makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

365. The HDA also led to the formation of interpersonal relationships and an organization between Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each Distributor and Manufacturer Defendant is a member.

366. The HDA and each Distributor Defendant sought the active membership and participation of Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

367. The HDA touted the benefits of membership to Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”

368. Distributor Defendants and the HDA used membership in that organization as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

369. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants. The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

370. After becoming members, Distributor and Manufacturer Defendants were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.
- c. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain.” Participation in this committee includes distributors and manufacturer members.
- d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management

and quality improvement.” Participation in this committee includes distributors and manufacturer members.

- e. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.
- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.
- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.
- h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.
- i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.

371. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the RICO Enterprise’s organization.

372. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and Distributor Defendants advertise these conferences to Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.” The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.” HDA conferences and the organization as a whole functioned as significant opportunities for Manufacturer and Distributor Defendants to interact at a high-level of leadership. And it is clear that Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

373. Defendants also maintained their interpersonal relationships by working together and exchanging information with the purpose of driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs. Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to Distributor Defendants for sales of prescription opioids.¹³⁵ As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an

¹³⁵ Lenny Bernstein & Scott Higham, *The Government’s Struggle to Hold Opioid Manufacturers Accountable*, WASH. POST, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also* Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letters From Sen. Claire McCaskill, (March 28, 2017), <https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), <http://www.purduepharma.com/payers/managed-markets/>.

industry-wide practice whereby Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.¹³⁶

374. On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, Distributor Defendants provided Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, ship notices, acknowledgements, and invoices.¹³⁷ The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct Distributor Defendants on how to most effectively sell the prescription opioids.

375. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturer Defendants likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by Defendants as a tool to violate their reporting and anti-diversion duties.

376. Taken together, the interaction and length of the relationships between and among Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to

¹³⁶ *Id.*

¹³⁷ Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

engage in the unlawful sale of prescription opioids. The HDA and PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of all Defendants were in communication and cooperation.

377. As stated above, the PCF has been lobbying on behalf of Manufacturer and Distributor Defendants for more than a decade, who, from 2006 to 2016, collectively funneled over \$740 million through the organization into lobbying efforts across the country on various issues including opioid-related measures. Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.

378. As described above, Defendants began working together as early as 2006 through the PCF and HDA to promote the common purpose of their enterprise.

379. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. Defendants' Conduct

380. The members of the Opioid Promotion Enterprise worked together to further the enterprise, by and among the following manner and means:

- a. Jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe and effective for the treatment of chronic, long-term pain;
- b. Concealing the addictive qualities of the opioids from prescribers and the public;
- c. Misleading the public about the addictive quality and safety and efficacy of opioids;
- d. Otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

- e. Illegally marketing, selling and/or distributing opioids; and
- f. Collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe or ineffective.

381. To achieve their common goals, Manufacturing Defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic pain as described herein, and they actively published misleading information to change the minds of those who already thought opioids to be dangerous. The Manufacturing Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids. They did all of this knowingly and intentionally and accomplished it by working together through relationships formed as part of a common enterprise.

382. During the time period alleged in this Complaint, Defendants exerted control over, conducted, and/or participated in the RICO Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits.

383. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

384. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids. Defendants disseminated false and

misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

385. Defendants paid nearly \$800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

386. Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

387. Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids. Defendants lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

388. Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

389. Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by Defendants.

390. Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The “know your customer” questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

391. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings.

392. Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders—all for failure to report suspicious orders.

393. Defendants’ scheme had a decision-making structure that was driven by Manufacturer Defendants and corroborated by Distributor Defendants. Manufacturer Defendants worked together to control the state and federal governments’ response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

394. Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants.

Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

395. Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders.

Defendants influenced the DEA production quotas in the following ways:

- a. Distributor Defendants assisted the enterprise and Manufacturer Defendants in their lobbying efforts through the PCF;
- b. Distributor Defendants invited the participation, oversight and control of Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. Distributor Defendants provided sales information to Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;
- d. Manufacturer Defendants used a chargeback program to ensure delivery of Distributor Defendants' sales information;
- e. Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]."
- f. Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

- g. Manufacturer Defendants used Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of Distributor Defendants by the DEA for failure to report suspicious orders;
- j. Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA; and
- k. The scheme devised and implemented by Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

396. Manufacturer Defendants worked together through Front Groups to intentionally distribute false and misleading information intended to deceive the public about the effects of opioids for the purpose of marketing their dangerous product in service of the Opioid Promotion Enterprise, which in turn served the overall opioid RICO Enterprise by driving up demand for opioids.

C. Pattern of Racketeering Activity

397. Defendants conducted and participated in the conduct of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. §1961(B), including mail fraud (18 U.S.C. §1341) and wire fraud (18 U.S.C. §1343); and 18 U.S.C. §1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

D. Mail and Wire Fraud

398. Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including Plaintiff, by knowingly conducting or participating in the conduct of the RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

399. Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity, *i.e.* violations of 18 U.S.C. §§1341 and 1343, within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by Defendants’ regular use of the facilities, services, distribution channels, and employees of the RICO Enterprise. Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

400. Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

401. In executing the illegal scheme, Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

402. Defendants' predicate acts of racketeering include, but are not limited to:¹³⁸

- a. Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and

¹³⁸ 18 U.S.C. §1961(1).

sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

403. Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of Defendants' illegal scheme:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and facilitated Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. §827;
- g. Documents and communications related to Defendants' mandatory DEA reports pursuant to 21 U.S.C. §823 and 21 C.F.R. §1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;

- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the PCF;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

404. Manufacturer Defendants' specific acts of mail and wire fraud in furtherance of the Opioid Promotion Enterprise include but are not limited to,

- a. The Federation of State Medical Boards (FSMB)'s publication of opioid prescribing guidelines entitled "Responsible Opioid Prescribing," by Fishman;
- b. The FSMB's publication of "Revised and Expanded 2nd Edition [of] Responsible Opioid Prescribing[:] A Guide for Michigan Clinicians";
- c. The American Pain Foundation (APF)'s publication of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families";
- d. The American Academy of Pain Medicine ("AAPM")'s "consensus statement" and educational programs featuring Fine;
- e. False or misleading communications to the public and to regulators;
- f. Sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

- g. Documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- h. Documents to process and receive payment for opioids, including invoices and receipts;
- i. Payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;
- j. Deposits of proceeds; and
- k. Other documents and things, including electronic communications.

405. On information and belief, Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

406. Manufacturer Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. Specifically, the Manufacturer Defendants made misrepresentations about opioids on their websites, YouTube and through online ads, all of which were intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

407. Manufacturer Defendants also communicated by U.S. Mail, by interstate facsimile and by interstate electronic mail with various other affiliates, regional offices, divisions, distributors and other third party entities in furtherance of the scheme. The mail and wire transmissions described herein were made in furtherance of the Manufacturer Defendants' scheme and common course of conduct to deceive prescribers and consumers and lure consumers into purchasing opioids, which Manufacturer Defendants knew or recklessly

disregarded as being unsafe and ineffective for chronic long-term pain and addictive. The Manufacturer Defendants utilized mail and wire transmissions to create an extensive campaign that advertised the exact opposite message: that opioids were safe and effective and rarely if ever addictive.

408. Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

409. At the same time, Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

410. Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

411. Defendants communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

412. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, that required the Defendants to annually certify in writing that they had implemented effective compliance programs and were otherwise in compliance with laws

and regulations regarding, among other things, the manufacture and distribution of opioids.

Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion RICO Enterprise's operation and goals, including false and misleading certifications required annually under the following:

- a. Section V of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharmaceuticals, Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014)
- b. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014);
- c. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson (fully executed on Oct. 31, 2013); and
- d. Section III of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

413. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

414. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities and other criminal activity have been deliberately hidden and cannot be alleged without access to Defendants' books and records. But Plaintiff has described the types of, and in some instances, occasions on which numerous predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the items and documents described in the preceding paragraphs.

415. Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. §1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for Defendants.

416. Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

E. Criminal Activity in Relation to Entities and Scheme

417. Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that Defendants were filling on a daily basis—leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

418. Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

419. Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

420. The predicate acts all had the purpose of generating significant revenue and profits for Defendants while Plaintiff was left with substantial injury to its interests through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by Defendants through their participation in the RICO Enterprise and in furtherance of its fraudulent scheme.

421. The pattern of racketeering activity and the RICO Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the RICO Enterprise.

422. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

423. Defendants conducted and participated in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

424. Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this

subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony.¹³⁹

F. Defendants' Knowledge

425. Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including Manufacturer Defendants' applications for production quotas. Specifically, Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

426. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8K with the SEC announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.

427. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA. The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in

¹³⁹ 21 U.S.C. § 483(d)(1).

particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking “Shouldn’t the DEA be contacted about this?” and adding that she felt “very certain this is an organized drug ring.” Despite knowledge of the staggering number of pills being issued in Los Angeles, and internal discussion of the problem, “Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”

428. Mallinckrodt also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt’s response was that everyone knew what was going on in Florida, but they had no duty to report it.

429. These examples reflect the Defendants’ pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. §1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of

controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related

to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California and Denver, Colorado;

- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

430. These actions against them confirm that Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate that Manufacturer Defendants were aware of the enforcement against their distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

G. Defendants' RICO Liability

431. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court.

432. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

433. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and its community. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or Plaintiff. Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

434. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

435. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

436. Defendants are liable to Plaintiff for under RICO.

H. RICO Damages

437. Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injuries because Plaintiff paid for costs associated with the opioid epidemic. These harms are on-going.

438. Plaintiff's injuries, were, and are being, proximately caused by Defendants' racketeering activities. But for Defendants' conduct, Plaintiff would not have paid the exorbitant costs and expenditures required as a result of the epidemic affecting the City of Dawson.

439. Plaintiff has injuries that were directly caused by Defendants' racketeering activities.

440. Plaintiff seeks all legal and equitable relief as allowed by law, including but not limited to, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre and post-judgment interest.

COUNT VI
RICO CONSPIRACY
(18 U.S.C. § 1962(d))
(Against All Defendants)

441. Plaintiff incorporates by reference all preceding paragraphs.

442. At all relevant times, Defendants were associated with the RICO Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity. Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions.¹⁴⁰

443. Defendants conspired to violate Section 1962(c), as alleged more fully in Count V, by conducting the affairs of the RICO Enterprise through a pattern of racketeering activity, as incorporated by reference herein.

COUNT VII
GEORGIA RICO
(O.C.G.A. § 16-14-1, et seq.)
(Against All Defendants)

¹⁴⁰ 18 U.S.C. § 1962(d).

444. Plaintiff incorporates by reference all preceding paragraphs.

445. Under Georgia law, Plaintiff may institute this action as an “aggrieved person.”¹⁴¹

446. The Georgia RICO Act states that “[i]t shall be unlawful for any person, through a pattern of racketeering activity or proceeds derived therefrom, to acquire or maintain, directly or indirectly, any interest in or control of any enterprise, real property, or personal property of any nature, including money.”¹⁴²

447. Defendants have engaged in “Racketeering Activity”, to-wit:

- a. “Commit[ing], [or] attempting to commit, or to solicit, coerce, or intimidate another person to commit any crime which is chargeable by indictment under the laws of [Georgia] involving” violations of The Georgia Controlled Substances Act;¹⁴³
- b. “Any act . . . involving . . . dealing in narcotic or dangerous drugs;”¹⁴⁴ and
- c. “Any conduct defined as ‘racketeering activity’ under 18 U.S.C. § 1961 (1).”¹⁴⁵

448. Defendants violated the Georgia RICO Act by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of Section 16-14-4(a).¹⁴⁶

449. Defendants’ Opioid Diversion Enterprise existed as an “enterprise” as defined in the Georgia RICO Act.¹⁴⁷

¹⁴¹ O.C.G.A. § 16-14-6(b).

¹⁴² O.C.G.A. § 16-14-4(a).

¹⁴³ O.C.G.A. § 16-14-3(8).

¹⁴⁴ O.C.G.A. § 16-14-3(5)(B).

¹⁴⁵ O.C.G.A. § 16-14-3(5)(C).

¹⁴⁶ O.C.G.A. § 16-14-4(a).

¹⁴⁷ O.C.G.A. § 16-14-3(3).

450. Defendants have engaged in “Racketeering Activity”, by, within the last 4 years, “committing at least two such acts of racketeering activity in furtherance of one or more . . . schemes, or transactions that have the same or similar intents, results,... victims, or methods of commission or otherwise are interrelated by distinguishing characteristics and [which] are not isolated incidents.”

451. Defendants acquired and maintained property through a pattern of racketeering activity and/or through the proceeds derived from a pattern of racketeering activity.

452. Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injuries.

453. Plaintiff’s injuries, and those of the citizens of Plaintiff’s Community, were proximately caused by Defendants’ racketeering activities.

454. But for Defendants’ conduct, Plaintiff would not have paid the health services and law enforcement services and other expenditures required as a result of the plague of drug-addicted residents.

455. Plaintiff’s injuries and those of its citizens were directly caused by Defendants’ racketeering activities.

456. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

457. Plaintiff seeks all legal and equitable relief as allowed by law, including but not limited to, actual damages, treble damages, punitive damages, equitable relief, attorney’s fees, and all costs and expenses of investigation and suit and pre and post-judgment interest.¹⁴⁸

COUNT VIII

¹⁴⁸ O.C.G.A. § 16-14-6(b) & (c).

GEORGIA DRUG DEALER LIABILITY ACT
(O.C.G.A. § 51-1-46, et seq.)
(Against All Defendants)

458. Plaintiff incorporates by reference all preceding paragraphs.

459. Georgia’s Drug Dealer Liability Act (DDLA),¹⁴⁹ provides a civil remedy against participants in “illegal marketing” of controlled substances for “damages to persons in a community as a result of illegal drug use.”¹⁵⁰

460. The DDLA defines “participat[ion] in illegal marketing” as “[m]anufacturing, distributing, or delivering or attempting or conspiring to manufacture, distribute, or deliver, a controlled substance” in violation of federal or state law.

461. A controlled substance within the meaning of the DDLA is defined as a substance referenced under O.C.G.A. § 16-13-26(4), which, in turn, is defined as “a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 C.F.R. Part 1308.”¹⁵¹

462. Defendants distributed prescription opioids which are included within this list and are therefore controlled substances, including but not limited to, hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, Opana, and Lortab.

463. Defendants did so in violation of state and federal laws such as those which require registered distributors of controlled substances to report suspicious orders.

464. Among the persons to whom the DDLA provides a remedy is “[a] . . . governmental entity, . . . or other legal entity that financially supports a drug treatment or other assistance

¹⁴⁹ O.C.G.A. § 51-1-46, et seq.

¹⁵⁰ O.C.G.A. § 51-1-46(d).

¹⁵¹ O.C.G.A. § 51-1-46(c)(1).

program for, or that otherwise expends money or provides unreimbursed service on behalf of the individual drug user.”¹⁵²

465. Plaintiff is a governmental entity that expended significant sums of money as a result of the illegal distribution of opioids in the City of Dawson.

466. One of the intents of the DDLA, among others, is “to shift, to the extent possible, the cost of damage cause by the existence of the illegal drug market in a community to those who illegally profit from that market.”¹⁵³ With the exception of Colombian drug cartels, perhaps no single entity in history has profited more from the illegal drug market than any single one of the Defendants.

467. A governmental entity may bring an action and recover damages under the DDLA on behalf of a person injured by an individual drug abuser for injury resulting from an individual’s use of an illegal drug” from “a person who participated in illegal marketing of the controlled substance.”¹⁵⁴

468. The definition of a person injured by an individual drug abuser includes “[a] . . . governmental entity, . . . or other legal entity that financially supports a drug treatment or other assistance program for, or that otherwise expends money or provides unreimbursed service on behalf of the individual drug user.”¹⁵⁵

469. An “individual drug abuser” is one who uses a who uses a controlled substance that is not obtained directly from or pursuant to a valid prescription or order of a practitioner who is

¹⁵² O.C.G.A. § 51-1-46(d)(2)(D).

¹⁵³ O.C.G.A. § 51-1-46.

¹⁵⁴ O.C.G.A. § 51-1-46(d)(1).

¹⁵⁵ O.C.G.A. § 51-1-46(d)(2)(D).

acting in the course of the practitioner's professional practice or which use is not otherwise authorized by state law.¹⁵⁶

470. Upon information and belief, individuals acquired and used hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, and/or Opana in the City of Dawson without a valid prescription and/or in a manner not authorized by state law.

471. Those who did so are “individual drug user[s]” under the DDLA.¹⁵⁷

472. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages.¹⁵⁸

473. Market share liability obtains if “(A) [t]he defendant was participating in the illegal marketing of the market area controlled substance at the time the individual abuser obtained or used that market area controlled substance; and (B) [t]he individual abuser obtained or used the market area controlled substance, or caused the injury, within the defendant's market area.”¹⁵⁹

474. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached the City of Dawson during all times relevant to this complaint. For purposes of the DDLA, Defendants’ “market area for the controlled substance” is the entire state of Georgia, because Defendants participated in the illegal drug market by distributing 650 grams or more of a “specified controlled substance.”¹⁶⁰

475. As noted by the Georgia Attorney General’s Office, the Georgia market for opioid pills prescribed between June 2016 and May 2017 reached 541 million individual doses, or 54

¹⁵⁶ O.C.G.A. § 51-1-46(c)(2).

¹⁵⁷ O.C.G.A. § 51-1-46(c)(2).

¹⁵⁸ O.C.G.A. § 51-1-46(e).

¹⁵⁹ O.C.G.A. § 51-1-46(e).

¹⁶⁰ O.C.G.A. §§ 51-1-46(c)(1)(6) & (e)(1)(D).

per Georgia Resident. Given that a single oxycodone tablet, on information and belief, weighs approximately 135 mg and contains at least 10 mg of opioid, there can be no question that each Manufacturer Defendant far exceeded the 650 grams level.

476. Manufacturer Defendants knowingly failed to implement effective controls and procedures in their supply chains to guard against theft, diversion, and abuse of prescription opioids, and failed to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

477. As a result, Manufacturer Defendants knowingly disseminated massive quantities of prescription opioids for distribution to the City of Dawson, allowing development of pills mills in the subject Community that impacted the City of Dawson directly.

478. Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including “pill mills” as well as and other drug dealers, knowing that such opioids would be illegally trafficked and abused.

479. The diversion of prescription opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of the City of Dawson.

480. Having knowingly participated in the illegal distribution of the Schedule II controlled substances, specifically prescription opioids described in this Complaint, in brand name or generic form, which were purchased or obtained by residents of the City of Dawson including those that were acquired from distribution channels in which Defendants were only market participants.

COUNT IX

UNFAIR OR DECEPTIVE TRADE PRACTICES
(Against All Defendants)

481. Plaintiff incorporates by reference all preceding paragraphs.

482. Defendants violated O.C.G.A. §10-1-370, et seq., because they engaged in deceptive trade practices in this state.

483. Defendants engaged, and continue to engage in, repeated and willful unfair, unconscionable, and deceptive practices in the conduct of commerce, including the deceptive omission of material facts.

484. Defendants' deceptive behavior has created confusion and misunderstanding as to the approval or certification of goods or services.

485. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels, but Defendants failed to report and/or prevent the diversion of highly addictive prescription drugs.

486. Defendants acted deceptively in giving the false impression that they were performing this duty when in fact they were not and knew they were not.

487. Defendants failed to disclose the material facts that they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders.

488. But for these material factual omissions, Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

489. Manufacturer Defendants wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

490. Manufacturer Defendants wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

491. Manufacturer Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, which tended to deceive and did in fact deceive both prescribers and consumers.

492. Manufacturer Defendants carried out a concerted campaign to falsely create the perception that opioids are safe and effective in treating non-cancer pain.

493. State law prohibits representing that goods or services have sponsorship, approval, characteristics, uses, or benefits that they do not have. State law further prohibits representing that goods are of a standard, quality, or grade if they are of another.

494. Because of the dangerously addictive nature of opioids, Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused an opioid epidemic in Georgia and specifically in the City of Dawson.

495. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to deceive the State, the public, Plaintiff's Community, and Plaintiff.

496. Plaintiff seeks an injunction preventing Defendants from continuing to make statements in violation of O.C.G.A. § 10-1-370, et seq.

497. Plaintiff seeks recovery of costs and attorneys' fees in accordance with O.C.G.A. § 10-1-373.

498. The limitations period has been tolled, and Plaintiff has brought this action upon discovering the existence of the facts underlying the causes of action alleged herein, within the limitations period.¹⁶¹

PUNITIVE DAMAGES

499. Plaintiff re-alleges all paragraphs of this Complaint as if set forth fully herein.

500. By engaging in the above-described unfair and/or intentionally deceptive acts, Defendants acted with actual malice and with conscious disregard for the rights of others and/or in a reckless, wanton, willful, or gross manner.

501. Defendants actions had a great probability of causing substantial harm.

502. When such harm materialized, Defendants acted with a prolonged indifference to the dire consequences of their wrongful conduct.

503. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels.

504. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes.

505. Defendants not only failed to live up this duty, but actively sought to undermine it in order to increase the volume of drugs they could sell.

¹⁶¹ O.C.G.A. § 9-3-96.

506. Defendants chose profit over the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence.

507. Indeed, an award of punitive damages is necessary to deter future similar large-scale business operations that harm the public due to the massive profits Defendants were able to reap as a result of their wrongful actions.

508. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that gives rise to the presumption of a conscious indifference to consequences.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court:

- A. Enter judgment against Defendants jointly and severally and in favor of Plaintiff;
- B. Award damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- C. Award actual and treble damages based on the amount of Plaintiff's losses resulting from Defendants' violations of the Racketeer Influenced and Corrupt Organization Act ("RICO");
- D. Order the disgorgement of ill-gotten funds and award those funds to the victims of Defendants' wrongful conduct, including Plaintiff.
- E. Award pre-judgment and post-judgment interest as provided by law, and award such interest at the highest legal rate;
- F. Enter an order of abatement and permanent injunction against all Defendants prohibiting them from engaging in the unlawful conduct detailed herein, including over-promotion and over-supply of opioids in and around the City of Dawson;

G. Enter an order requiring Defendants to fund an “abatement fund” for the purpose of abating the opioid nuisances;

H. Award Plaintiff the costs of suit, including reasonable attorneys’ fees as provided by law; and

I. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted, this 19th day of June, 2019.

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/s/ Cale Conley

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